EXPRESS MAIL NO.: EL 477 037 728 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Busfield et al.	Confirmation No.: 6848
Serial No.: 09/610,118	Group Art Unit: 1644
Filed: June 30, 2000	Examiner: Decloux, Amy M.
For: GLYCOPROTEIN VI AND USES THEREOF	Attorney Docket No.: 7853-211

DECLARATION OF DR. DAVINDER GILL UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Davinder Gill, do hereby declare and state:

1. I am a co-inventor of the invention claimed in U.S. application Serial No. 09/610,118 (hereinafter "the '118 application"). I currently hold the title of Senior Scientist at Millennium Pharmaceuticals, Inc., assignee of the '118 application.

2. My academic and technical experience, and a list of my publications, are set forth in my *curriculum vitae*, attached hereto as Exhibit 1.

3. I have reviewed the '118 application, the claims pending in the '118 application, and the Office Action, mailed December 18, 2001. As I understand it, the claims of the '118 application are subject to a rejection based on the contention that the antibodies of the claimed invention are not described in the specification in such a way as to enable a person skilled in the art to make and/or use the antibodies of the claimed invention.

4. The specification of the '118 application coupled with information known as of the filing date of the '118 application provides sufficient guidance to enable a person skilled in the art to practice the claimed invention, without undue experimentation.

5. The specification of the '118 application teaches substantially purified antibodies comprising one or more complementarity determining regions ("CDRs") having an amino acid sequence of one or more of the CDRs encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit Number PTA-2442, wherein the antibody immunospecifically binds to a human TANGO 268 antigen. See, *e.g.*, the specification of the '118 application at page 11, line 25 to page 12, line 31 and page 85, line 20 to page 102, line 5.

6. As of the effective filing date of the '118 application, methods for producing antibodies comprising one defined CDR and several undefined CDRs were well-known to the skilled artisan. Barbas et al., 1992, Proc. Natl. Acad. Sci. USA 89: 4457-4461 (attached hereto as Exhibit 2) describes methods for generating antibodies in which all but one CDR (*i.e.*, the VH CDR3) remains constant. Jirholt et al., 1998, Gene 215: 471-476 (attached hereto as Exhibit 3) teaches methods for generating antibodies that differ in all three CDRs of the VH domain of an antibody (see, *e.g.*, Figure 1 of Jirholt). Soderlind et al., 1999, Immunotechnology 4: 279-285 ("Soderlind"; (attached hereto as Exhibit 4)) teaches methods for generating antibodies that differ in one to six of the CDRs of an antibody. In particular, Soderlind teaches methods for implanting one or more unknown CDR sequences into a defined master framework (see, *e.g.*, Figure 1 of Soderlind). Thus, as of the effective filing date of the '118 application, one of skill in the art would have been able to produce, without undue experimentation, an antibody comprising a CDR having an amino acid sequence of a CDR encoded by the cDNA insert of the plasmid deposited the ATCC® as patent deposit Number PTA-2442.

7. As of the effective filing date of the '118 application, methods for identifying antibodies that immunospecifically bind to a particular antigen were well-known to the skilled artisan. The specification of the '118 application, *e.g.*, at page 104, lines 18-29 teaches immunoassays for identifying antibodies which immunospecifically bind to a human TANGO 268 antigen. Immunoassays for identifying antibodies that immunospecifically bind to a particular antigen such as, *e.g.*, a human TANGO 268 antigen are also described, *e.g.*, in Chapter 14 of Harlow et al., eds, 1988, Antibodies A Laboratory Manual, Cold Spring Harbor, New York (attached hereto as Exhibit 5). Further, Soderlind teaches that antibodies comprising one or more unknown CDRs can be screened for those antibodies which immunospecifically bind to a particular antigen and

Soderlind et al., 2000, Nature Biotechnology 18: 852-856 (attached hereto as Exhibit 6), a post-filing date publication, demonstrates the successful selection of antibodies comprising unknown CDRs which immunospecifically bind to a particular antigen.

8. In summary, the '118 application coupled with information well-known to a person skilled in the art as of the effective filing date would have enabled the person skilled in the art using routine methods to produce and identify an antibody comprising a CDR having an amino acid sequence of a CDR encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit Number PTA-2442, wherein the antibody immunospecifically binds to a human TANGO 268 antigen.

9. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 6/18/02

Dr. Davinder Gill

Attachments:

Exhibit 1: *Curriculum Vitae* of Dr. Davinder Gill

Exhibit 2: Barbas et al., 1992, Proc. Natl. Acad. Sci. USA 89: 4457-4461

Exhibit 3: Jirholt et al., 1998, Gene 215: 471-476

Exhibit 4: Soderlind et al., 1999, Immunotechnology 4: 279-285

Exhibit 5: Chapter 14 of Harlow et al., eds, 1988, Antibodies A Laboratory Manual, Cold Spring Harbor, New York

Exhibit 6: Soderlind et al., 2000, Nature Biotechnology 18: 852-856